Virtual Mentor
American Medical Association Journal of Ethics
October 2002, Volume 4, Number 10: 288-291.

CASE AND COMMENTARY
Clinician and Researcher, Commentary 1
Commentary by Timothy F. Murphy, PhD

Case
Internist Michael Hoover has been in practice in a mid-sized city for 12 years. He is a member of an internal medicine group practice, so he frequently sees patients of his partners when their own physician is unavailable. The group's patients range in age from early 30s to late 80s, the majority in the 40- to 75-year range. Those whom Dr. Hoover sees on a regular basis have hypertension, heart disease, headaches, arthritis, or respiratory and other organ system complaints, often related to aging. Some have cancers; a few have chronic conditions such as diabetes and lupus. Most of the group's patients have some health insurance or Medicare; 8 to 10 percent of care is uncompensated.

Dr. Hoover is prompted to think about the illnesses and demographics of his patients in this way when he receives a letter from a contract research organization that matches pharmaceutical companies that are conducting clinical research to physicians. One of the contract organization's current client companies has an anti-depressant drug in Phase III randomized clinical trials and is looking for physicians who can participate. The company is particularly interested in testing the drug's effectiveness on men. They would like Dr. Hoover to enroll 25 participants.

Initially, Dr. Hoover is eager to participate. He has a significant number of male patients who, he thinks, suffer from depression of various kinds—some because they are aging and losing abilities they once had or have chronic illness that brings increasing disability with it. Others because they have lost a wife, or a job, or their rights to see their children. Still others seem depressed regardless of their current life circumstances. Most have been reluctant to try medication or to see counselors of any sort. "If only I could get a good night's sleep," they say, or "had a little more energy," or "had a job," or "could see my kids." They rarely entertain the notion that treating depression might enable them to get more sleep, or a job, or have more energy, because they don't think they're depressed.

Dr. Hoover reckons that, given the good relationship he has with his patients, and by offering them the opportunity to do their part for medical science, he could persuade many of his depressed male patients to participate in the study. As the decision time draws close, however, Dr. Hoover begins to have second thoughts. The pharmaceutical company will pay him $3,000 for each patient he enrolls in the study. He will follow the participating patients for 2 years. These visits that will be

free to the participants. Is it taking advantage of his patients' trust that he can probably "persuade" them to participate, he wonders? Does the offer of a free visit every 3 months constitute financial pressure for his jobless patients with depression? Is the $3,000 per subject an incentive for him to participate? Will the clinician and researcher roles conflict?

The study is double-blind, so Dr. Hoover will not know which patients are receiving the trial drug and which are not. Dr. Hoover has no financial interest in the company that is conducting the trials, and believes that a good anti-depressant with limited side effects would be a therapeutic advantage over what is currently available. If he doesn't participate, will the doctor who the contract organization ends up recruiting handle the patient trust and conflicts of interest issues better than he can?

Under what conditions, if at all, should Dr. Hoover agree to be a clinician-researcher for the pharmaceutical company testing its anti-depressant drug?

Commentary 1

Capitation fees are financial incentives that sponsors of clinical trials offer to physicians who help identify and enroll subjects in studies of medical drugs and devices. In the case here, Dr. Hoover might enroll as many as 25 subjects over the course of 2 years. At $3,000 per subject, he could take in $75,000. The purposes for which this money can be used depend on the rules of his group practice. One use would be to cover the costs of running the study. For example, Dr. Hoover could use the money to hire an assistant to coordinate the study and make sure that appointments are kept and data are sent to the pharmaceutical corporation as appropriate. Some medical practices might allow Dr. Hoover to use any money left over for professional purposes. For example, he could use the money to attend medical conferences and seminars or to buy medical equipment. Depending on the rules of his group practice, he might even be able to use the money as part of his salary or for personal purposes.

Dr. Hoover wonders whether it is ethical to involve his patients in this study or whether he has conflicts of interest, both medical and financial. A conflict of interest involves a situation in which someone has a private or personal interest that could influence the way in which professional decisions are made. In conflicts of interest, people could make decisions that serve their own interests rather than the interests of the people they have an obligation to serve.

The notion of *equipoise* should be helpful to Dr. Hoover in coming to a decision about whether it is appropriate to enroll his patients in this trial. *Equipoise* refers to indeterminacy about whether one medical drug or device is better than another. A clinical trial is designed to resolve this uncertainty. Before such studies begin, there should be good reasons for thinking that a new drug should be tested: it has shown strong promise in animals; there are scientific reasons for expecting it to offer superior therapy; or it might be an improvement in that it could be taken only once

a day rather than 4 times a day. It is this expectation that the new intervention is superior in some way and uncertainty about that superiority that justify asking people to enroll in clinical trials. If Dr. Hoover is convinced *that* there are good reasons to expect this drug to be better in some way than other drugs *and that* it is unclear whether this new drug is in fact superior, he is justified in asking patients to enroll in the study. In other words, he has no reason to think that he is depriving a patient of a clear benefit by offering that patient the opportunity to take a new—and possibly better—drug.

Enrolling patients will bring money to Dr. Hoover, and he therefore wonders whether capitation fees generate a financial conflict of interest. One danger arising from capitation fees is that Dr. Hoover might be tempted to enroll patients who are not appropriate for this study. The way to control this temptation is to ensure that the study in question has very clearly identified inclusion and exclusion criteria. These criteria spell out the subjects of interest to the research, and when defined in a precise way they can work against dubious enrollment practices. Dr. Hoover should also remember that it is not his decision to enroll patients in the study; that decision belongs to them. In order to minimize any conflict of interest he should make sure that the patients receive thorough information about the study in a way that lets them decide free from any possible bias from him about the importance of enrolling.

Federal regulations governing clinical research require that researchers disclose certain financial aspects of subjects' involvement: whether they will receive any free care, compensation, or treatment in the case of an emergency. For some people, free medical care—even experimental medical care—can influence decisions about enrolling in clinical trials. To be sure, some people might not get medical care except for their participation in clinical trials. It is not unethical to offer free medical services as part of a clinical trial. If those services cross the line to the point where they have a undue influence in decisions to enter the trials, Dr. Hoover would be right to wonder how free his patients were to make their own decisions about enrolling. Free services should not force people to accept risks they would not otherwise accept.

Federal regulations *do not* require researchers to disclose capitation fees to subjects, and the vast majority of researchers make no such disclosures. Dr. Hoover is not alone in wondering whether there are ethical concerns here. Good practices in study design and informed consent should work to prevent any lapses of judgment on Dr. Hoover's part. However, potential subjects could be in a better position to evaluate *for themselves* whether the offer of enrollment is disinterested if they knew what benefits the researcher would receive. If Dr. Hoover is worried that capitation fees might influence his judgment in some way, or if Dr. Hoover wanted to avoid even the appearance of a conflict of interest, he could exceed federal requirements and disclose the terms of his own financial arrangements with the sponsors of the research.

Timothy F. Murphy, PhD is a visiting scholar at The Institute for Ethics of the American Medical Association and professor of philosophy in the biomedical sciences at the University of Illinois College of Medicine at Chicago.

The people and events in this case are fictional. Resemblance to real events or to names of people, living or dead, is entirely coincidental. The viewpoints expressed on this site are those of the authors and do not necessarily reflect the views and policies of the AMA.